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REMARKS

Claims 1-25 are pending in the application. The Examiner has indicated that Claim 12 is allowed. The Examiner has also indicated that claim 13 would be allowable if rewritten or amended to overcome the objection set forth in the Office Action of March 26, 2003, and that claims 14-17 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims and to overcome the objection to claim 13 as set forth in the Office Action of March 26, 2003. Claims 1, 2, 7, 8, 13, 18, 19 and 22 (and thus dependent claims 3-6, 9, 10, 14-17, 20 and 21) have been amended. Claims 11, 23, 24 and 25 have been cancelled. Support for the amendments can be found in the specification as filed. No new matter has been added by way of amendment. Reexamination and reconsideration of the claims are respectfully requested.

Conditions for Receiving the Benefit of an Earlier Filing Date

The Examiner has indicated that Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120 because an application in which the benefit of an earlier application is desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet. The specific reference to any prior non-provisional application, in this case Application 09/551,778, now U.S. Patent No. 6,504,084, must include the relationship between the applications.

Applicants have amended the specification to indicate the fact that the instant application is a divisional of, and claims benefit of and priority to, Application 09/551,778, now U.S. Patent No. 6,504,084. This amendment is supported by the Utility Patent Application Transmittal papers submitted on January 15, 2002, on page 3, item 16, which indicates that the instant application is a divisional application.

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Title

The Examiner has objected to the title of the invention as not being descriptive of the instant invention. Applicants have amended the title to "MAIZE NPR1 PROMOTER AND METHODS OF USE IN PLANT GENE EXPRESSION", in order to more clearly indicate the invention to which the claims are directed. This amendment is shown in the previous section entitled "Amendments to the Specification", beginning on page 2 of the instant response. No new matter is added by way of the amendment to the title.

Abstract

The Examiner has objected to the abstract of the invention as not being descriptive of the instant invention. Applicants have amended the abstract as shown in the previous section entitled "Amendments to the Specification", beginning on page 2 of the instant response. Applicants assert that the new abstract is clearly indicative of the invention to which the claims are directed. No new matter is added by way of the amendment to the abstract.

Claim Objections

The Examiner has objected to claims 2-10 and 13-21 because of informalities relating to the use of improper articles. Applicants have amended claims 2, 8, 13 and 19 by correcting the use of improper articles, thereby obviating the claim objections as they apply to claims 2, 8, 13, and 19 as well as their respective dependent claims.

The Rejection of Claims Under 35 U.S.C. §112, First Paragraph, Should be Withdrawn Enablement

The Examiner has rejected claims 1-11 and 22-25 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a promoter of SEQ ID NO: 5, expression constructs comprising the promoter, cells, plants and seeds comprising the constructs, and methods of using the constructs to express heterologous nucleic acids in a plant, does not reasonably provide enablement for any nucleic acid that hybridizes to SEQ ID NO: 5, that has 70, 80 or 90% identity to

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SEQ ID NO: 5 or that comprises 20 contiguous nucleotides of SEQ ID NO: 5, expression constructs comprising the nucleic acid, cells, plants and seeds comprising the constructs, and methods of using the constructs to express heterologous nucleic acids in a plant. The Examiner continues that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants respectfully disagree.

The Examiner states that the instant specification fails to provide guidance for exact hybridization or amplification conditions and probes/primers to use in isolation of nucleic acids other than SEQ ID NO: 5. Applicants respectfully disagree. Applicants have provided extensive guidance to be used in the selection of stringency conditions based on the desired outcome. See page 18, line 26 through page 20, line 14 of the specification as originally filed. Applicants have provided an extensive discussion of hybridization conditions and requirements specifically on page 19, lines 8-15 of the instant specification. Applicants have also provided guidance for post-hybridization wash conditions on page 19, line 17 through page 20, line 14, of the specification. The design of appropriate primers has been outlined by the Applicants on page 26, line 27 through page 27, line 19 of the specification. Furthermore, Applicants have given guidance regarding the design and use of probes on page 37, lines 18-34 of the specification. In view of the extensive guidance provided, Applicants assert that the invention is clearly enabled as claimed. However, in order to further prosecution, Applicants have cancelled claims 11 and 23-25, and have amended claims 1 and 22 to remove reference to promoters comprising 20, 50 or 100 contiguous nucleotide segments of SEQ ID NO: 5. Applicants have also amended claim 1 to remove reference to nucleic acids that hybridize to SEQ ID NO: 5.

Applicants have amended claim 22 to claim only those isolated nucleic acids capable of driving expression of a heterologous gene wherein the nucleic acid comprises at least 500 contiguous nucleotides of SEQ ID NO: 5. Applicants have clearly provided support in the specification as filed for fragments of SEQ ID NO: 5 which retain biological activity, specifically those which are capable of driving expression of a heterologous gene. See page 38, line 24 through page 39, line 18, of the specification as originally filed. Applicants stress that the claim is

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exclusively directed to those fragments of SEQ ID NO: 5 which retain biological activity. Creating 500 nucleotide fragments of SEQ ID NO: 5 and testing them for promoter activity is routine in the art and does not constitute undue experimentation.

Written Description

The Examiner has rejected claims 1-11 and 22-25 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner states that claims 1 and 11 do not describe the function of the claimed nucleic acids. Claim 11 has been cancelled. Claim 1 has been amended to specifically recite that the nucleic acid is a promoter. The use of the term "promoter" is descriptive of the activity of the nucleic acid. As defined on page 17, lines 23-27 of the specification as originally filed, a promoter is a region of DNA upstream from the start of transcription and involved in recognition and binding of RNA polymerase and other proteins to initiate transcription.

The Examiner states that the Applicants have not, in fact, described DNA molecules that hybridize to SEQ ID NO: 5, that have 70, 80 or 90% identity to SEQ ID NO: 5, or that are promoters comprising at least 20 contiguous nucleotides of SEQ ID NO:5 within the full scope of the claims, and the specification fails to provide an adequate written description of the invention. Applicants respectfully disagree. In view of the remarks and claim amendments previously discussed, promoters that have 70, 80 or 90% identity to SEQ ID NO: 5, or that are promoters comprising at least 20 contiguous nucleotides of SEQ ID NO: 5 are no longer being claimed.

Accordingly, Applicants request that the rejection of claims 1-11 and 22-25 under 35 U.S.C. §112, first paragraph, be withdrawn.

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The Rejection of Claims Under 35 U.S.C. §112, Second Paragraph, Should be Withdrawn

The Examiner has rejected claims 1-11 and 18-25 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Applicants thank the Examiner for her suggestions on claim amendments.

Applicants have amended claim 1, to remove part (c). Applicants have also amended claim 1 in order to correct the antecedent basis for claim 8, part (a). Applicants have further amended claim 19, part (a) to correct the dependency and the antecedent basis.

Applicants have amended claims 7 and 18 according to the Examiner's suggestion by the inclusion of "—wherein the seed comprises the recombinant expression cassette."

Applicants have amended claim 8, part (b) and claim 19, part (b) according to the Examiner's suggestion by the recitation of "regenerating a plant from the plant cell."

Applicants have amended claim 8, part (c) and claim 19, part (c) to remove the recitation of "allowing" expression.

Applicants have amended claim 22 according to the Examiner's suggestion by replacing "comprising" with "wherein the nucleic acid comprises."

Accordingly, Applicants respectfully request withdrawal of the rejections of claims 1-17 under 35 U.S.C. §112, second paragraph.

The Rejection of Claims Under 35 U.S.C. §102 Should be Withdrawn

The Examiner has rejected claim 1 under 35 U.S.C. §102(a) as being anticipated by SanMiguel *et al.* (1998, Gen Bank Accession No. AF050451). SanMiguel *et al.* teach an isolated nucleic acid that comprises a nucleic acid with 90.9% identity to SEQ ID NO: 5. The sequence taught by SanMiguel *et al.* is 1,231 nucleotides in length, and is a Zea Mays retrotransposon. SEQ ID NO: 5 of the instant invention is 2,715 nucleotides in length, and is a Zea Mays NPR-1 promoter. The sequence comparison results included in the Office Action of March 26, 2003, presented by the Examiner, indicate a match of 497 nucleotides between the two sequences. Although this 497 nucleotide portion of the two sequences has 90.9% identity, the two sequences do not have a significant identity over their full length. Furthermore, SanMiguel *et al.* do not

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teach the NPR-1 promoter of the instant invention. In view of these remarks and the amendments to the claims reciting only those sequences with at least 95% identity to SEQ ID NO: 5, Applicants assert that the sequence taught by SanMiguel *et al.* is not anticipatory of SEQ ID NO: 5.

The Examiner has rejected claim 1 under 35 U.S.C. §102(b) as being anticipated by Quayle *et al.* (1992, GenBank Accession No X58700). Quayle *et al.* teach a nucleic acid of 7622 nucleotides in length which is annotated as the Zea Mays ZMPMS2 gene for 19 kDa zein protein. SEQ ID NO: 5 of the instant invention is 2,715 nucleotides in length, and is an NPR-1 promoter sequence. The sequence comparison presented by the Examiner in the Office Action of March 26, 2003, indicates that the two sequences share a region of 83.0% identity, with a match of 454 nucleotides between the two sequences. Although this 454 nucleotide portion of the two sequences has 83.0% identity, the two sequences do not have a significant identity over their full length. In view of these remarks and the amendments to the claims, reciting only those sequences with at least 95% identity to SEQ ID NO: 5, Applicants assert that the sequence taught by Quayle *et al.* is not anticipatory of SEQ ID NO: 5.

The Examiner has rejected claims 1-10 under 35 U.S.C. §102(c) as being anticipated by Uknes *et al.* (U.S. Patent No: 5,986,082, filed December 1996). The Examiner states that Uknes *et al.* teach an isolated nucleic acid that comprises a promoter that would hybridize to SEQ ID NO: 5 under "highly stringent conditions", recombinant expression cassettes comprising this promoter, vectors, cells, plants and seeds comprising the recombinant expression cassette, and a method for expressing a heterologous nucleic acid in a plant. Applicants respectfully point out to the Examiner the exemplary high stringency conditions provided on page 19, lines 31-32 of the specification as originally filed. These conditions include hybridization in 50% formamide, 1 M NaCl, 1% SDS at 37°C, and a final wash in 0.1X SSC at 60 to 65°C. The following equation and information for hybridization appear in section 2.9.8 (Supplement 13) from Current Protocols in Molecular Biology, Edited by: Fred M. Ausubel, Roger Brent, Robert E. Kingston, David D. Moore, J.G. Seidman, John A. Smith, Kevin Struhl.

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$$T_m = 81 + 16.6 \log_{10} C_i + 0.4 [\% (G+C)] - 0.6 (\% \text{ formamide}) - 600/n - 1.5 (\% \text{ mismatch})$$

where

C_i = molar concentration of monovalent cations

n = length of the annealed product

In general, convenient hybridization temperatures in the presence of 50% formamide are 42°C for a probe which is 95-100% homologous to the target fragment, 37°C for 90-95% homology and 32°C for 85 to 90% homology (emphasis added).

Since the exemplary high stringency conditions recited in the specification as originally filed include hybridization in 50% formamide at 37°C, any target sequence less than 90% homology to SEQ ID NO: 5 will not hybridize to SEQ ID NO: 5. Applicants have reviewed U.S. Patent No. 5,986,082, which discloses the *Arabidopsis* NIM1 gene and various altered forms of this gene. Applicants are unable to find any promoter sequences taught by Uknes *et al.* Applicants are therefore unsure of which of the sequences taught by Uknes *et al.* the Examiner is referring to as being a promoter that would hybridize to SEQ ID NO: 5 under highly stringent conditions. Regardless, Applicants assert that the sequences taught by Uknes *et al.* would not hybridize to SEQ ID NO: 5 under highly stringent conditions because none of the sequences taught by Uknes *et al.* have 90% or higher homology to SEQ ID NO: 5. Furthermore, in view of the claim amendments removing reference to sequences which would hybridize to SEQ ID NO: 5 under "highly stringent conditions", Applicants assert that the teachings of Uknes *et al.* do not anticipate the claims of the present invention.

In view of the preceding remarks and claim amendments, Applicants respectfully request withdrawal of the rejections of the claims under 35 U.S.C. §102.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 U.S.C. §§112, first and second paragraphs and 35 U.S.C. §102 have been overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

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If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-1852.

Respectfully submitted,



Claire L. Moxon

(See: LIMITED RECOGNITION
UNDER 37 CFR § 10.9(b)
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